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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,103	11/08/2000	Mary Cismowski	60388-A-PCT-US/JPW/GJG/JB	2867

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	14

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/709,103	CISMOWSKI ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-85 and 87-93* is/are rejected.

7)☒ Claim(s) *86* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

This is a First Office Action on the Merits of the Application filed 8 November 2000 as a continuation of international application PCT/US99/10151 filed 7 May 1999 and claiming benefit of U.S. Provisional Applications 60/084,842, filed 8 May 1998, and 60/103,355, filed 7 October 1998. Receipt and entry of the preliminary amendment filed 8 November 2000 is acknowledged. This Office Action is a response to the "Amendment and Response" filed 2 December 2002 (Paper No. 15). All of the pending claims were canceled and new claims 79-93 were added in Paper No. 15.

Election/Restrictions

Applicant's election of Group I, directed to an isolated nucleic acid molecule encoding an AGS protein and vector and host cell comprising said nucleic acid molecule, in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 79-93 are presently pending and under consideration.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing

Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

A response to this office action must include a response to the Notice to Comply with the Sequence Rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The priority claim to PCT/US99/10151 is improperly made under both 35 U.S.C. § 119(a)-(d) and 35 U.S.C. § 120. Applicant should provide a substitute Declaration wherein priority to PCT/US99/10151 is claimed under 35 U.S.C. § 120 only.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79, 80, 83 and 89-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising nucleotides having a sequence which encodes a functional activator of G protein signaling (AGS) protein which comprises amino acids having a sequence which is at least 98% homologous to the sequence set forth as SEQ ID NO:2, does not reasonably provide enablement for nucleic acid molecules encoding non-functional AGS proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention: The claims are directed to an isolated nucleic acid molecule encoding a polypeptide comprising an amino acid sequence that is at least 98% homologous a polypeptide sequence set forth in the disclosure. Claims are further directed to a vector, host cell and method of using said nucleic acid molecule to produce the polypeptide.

Breadth of the claims: The claims are limited only to a nucleic acids encoding a polypeptide having a defined structural characteristic and thus encompass polypeptides that are non-functional or have functions that are not disclosed in the specification or prior art.

State and level of predictability in the art: The prior art does not generally provide a use for any and all polypeptides having structural similarity to a protein of known function, or nucleic acids encoding those polypeptides. In order to use a molecule without first engaging in undue experimentation, the skilled artisan must have a teaching of the function of that molecule or a teaching of how to divine function from the disclosed structure. To the extent that the claims are directed to polynucleotides encoding polypeptides that do not have the function of an AGS, the teachings of the prior art are silent with regard to what function those polypeptides might have or how they might be used.

Amount of direction provided by the inventor and Existence of working examples: The specification, beginning on page 41 and continued through page 66, teaches that a nucleic acid encoding an AGS polypeptide can be used to express said AGS polypeptide and further teaches a variety of uses for polypeptide having the function of an AGS. The examples additionally teach methods of testing polypeptides for AGS function. However, the disclosure does not teach how to use a polypeptide, or nucleic acid encoding a polypeptide, that does not function as an AGS.

Quantity of experimentation needed to make or use the invention: In the absence of any teaching in the specification or prior art regarding how one might use a nucleic acid encoding a polypeptide having 98% homology with an AGS protein wherein the polypeptide does not function as an AGS, the skilled artisan would have to engage in trial and error experimentation to divine a real world utility for the protein of unknown function. As the vast majority of such

proteins would have no function at all, the skilled artisan would have to test a large pool of polypeptides to find the very small fraction that might have some useful function other than that of an AGS. The amount of experimentation required would clearly be beyond what is routine in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 79-85 and 87-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Yen (2002) U.S. Patent No. 6,462,177.

Yen teaches an isolated nucleic acid comprising a sequence that encodes an AGS protein having an amino acid sequence that is 100% homologous to the sequence set forth as SEQ ID

NO:2 according to the isolated nucleic acids of claims 79-84 (see result 1 of the sequence alignment labeled us-09-709-103-2.p2n.rni attached to the citation). As the polypeptide encoded by the nucleic acid of Yen is identical to the polypeptide of SEQ ID NO:2, the functional limitation set forth in claims 82 and 87 (i.e. activates G protein-coupled signal transduction in a G protein- coupled receptor independent manner) is inherent to the polypeptide. Further, the nucleic acid of Yen is a human nucleic acid according to claims 83 and 88, and encodes the same AGS protein encoded by the sequences set forth as SEQ ID NO:1 and 3 (i.e. the polypeptide set forth as SEQ ID NO:2) according to claim 84, which nucleic acid has a sequence as set forth in SEQ ID NO:1 according to claim 85 (see especially result 1 of the alignment labeled us-09-709-103-1.rni).

In Example 2, beginning column 21, Yen teaches a vector comprising the nucleic acid described above, which vector is a recombinant expression vector, a host cell containing said vector, and a method for producing an AGS protein comprising culturing said host cell in a suitable medium. These teachings anticipate claims 89, 90, 91 and 92 respectively.

The nucleic acid, vector, host cell and method taught by Yen are the same as those taught in the instant application; therefore, the limitations of the claims are met by Yen.

Allowable Subject Matter

Claim 86 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
February 11, 2003

JAMES KETTER
PRIMARY EXAMINER